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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/713,836	11/14/2003	Kanwarpal S. Dhugga	1520	5758

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EXAMINER

KALLIS, RUSSELL

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 11/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/713,836	Applicant(s) DHUGGA, KANWARPAL S.	
	Examiner Russell Kallis	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 7 and 23-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 8-22 and 30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>8/29/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, claims 1-6, 8-22 and 30; SEQ ID NO: 1 and 2 in the reply filed on 8/22/2006 is acknowledged. No grounds for the traversal have been presented.

The requirement is still deemed proper and is therefore made FINAL. Claims 1-30 are pending. Claims 7 and 23-29 are withdrawn. Claims 1-6, 8-22 and 30 are examined.

Specification

The disclosure is objected to because of the following informalities: The specification refers to the data in Table 5 on page 77, lines 5-6 of the specification, however there is no Table 5 in the specification. Appropriate correction is required.

Claim Objections

Claims 1, 6, 14, and 22 are objected to because of the following informalities: The claims recite non-elected subject matter. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 1-6, 8-22 and 30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to a nucleotide sequence having at least 80% sequence identity to SEQ ID NO: 1; nucleotide sequence that hybridize to SEQ ID NO: 1 under conditions of unspecified stringency; and fragments of SEQ ID NO: 1 that encode a mannan synthase; and a method of altering galactomannan and a method of producing gum in a plant transformed therewith; and plants and plant cells thereof.

Applicants describe SEQ ID NO: 1 comprising a polynucleotide sequence that encodes SEQ ID NO: 2 a beta 1,4-mannan synthase.

Applicants do not describe any other mannan synthases that have at least 80% sequence identity to SEQ ID NO: 1 or hybridize to SEQ ID NO: 1 or comprise a fragment of SEQ ID NO: 1 and possess mannan synthase activity.

The Federal Circuit has recently clarified the application of the written description requirement to inventions in the field of biotechnology. The court stated that, "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus." *See University of California v. Eli Lilly and Co.*, 119 F.3d 1559; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

Applicants fail to describe a representative number of manna synthase encoding sequence that hybridize to SEQ ID NO: 1 or have at least 80% sequence identity to SEQ ID NO: 1.

Applicants only describe SEQ ID NO: 1 encoding SEQ ID NO: 2. Furthermore, Applicants fail to describe structural features common to members of the claimed genus of mannan synthases that are encoded by the polynucleotides that hybridize to SEQ ID NO: 1 or have at least 80% sequence identity to SEQ ID NO: 1. Hence, Applicants fail to meet either prong of the two-prong test set forth by *Eli Lilly*. Furthermore, given the lack of description of the necessary elements essential for mannan synthase activity, it remains unclear what features identify a mannan synthase. Since the genus of mannan synthases has not been described by specific structural features, the specification fails to provide an adequate written description to support the breadth of the claims.

Sequences that hybridize with SEQ ID NO: 1 under conditions of unspecified stringency and which are 80% complementary to SEQ ID NO: 1 encompass naturally occurring allelic variants, mutants of SEQ ID NO: 1, as well as sequences encoding proteins having no known mannan synthase activity, of which Applicant is not in possession. Accordingly, the specification fails to provide an adequate written description to support the genus of polynucleotide sequences encompassed by the hybridization language or percent identity language as set forth in the claims. (See Written Description guidelines published in Federal Register/Vol. 66, No.4/Friday, January 5, 2001/Notices: p.1099-1111).

Claims 1-6, 8-22 and 30 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for SEQ ID NO: 1, plants transformed therewith and methods thereof, does not reasonably provide enablement for polynucleotide sequence that have at least

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80% sequence identity to SEQ ID NO: 1, or that hybridize to SEQ ID NO: 1 under conditions of unspecified stringency. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claimed invention is not supported by an enabling disclosure taking into account the *Wands* factors. *In re Wands*, 858/F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988). *In re Wands* lists a number of factors for determining whether or not undue experimentation would be required by one skilled in the art to make and/or use the invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claim.

The claims are broadly drawn to a nucleotide sequence having at least 80% sequence identity to SEQ ID NO: 1; nucleotide sequence that hybridize to SEQ ID NO: 1 under conditions of unspecified stringency; and fragments of SEQ ID NO: 1 that encode a mannan synthase; and a method of altering galactomannan and a method of producing gum in a plant transformed therewith; and plants and plant cells thereof.

Applicants teach isolation of SEQ ID NO: 1 encoding a mannose synthase from an EST database of developing Guar seeds using motif comparison to processive beta glycosyl-transferases (Example 4 pages 52-54 specification) and correlation of the appearance of galactomannan in the endosperm of Guar seeds with the expression of SEQ ID NO: 1 i.e. transcriptional profiling (Example 7 page 55 specification); mannase synthase activity in

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transgenic somatic soybean embryos expressing SEQ ID NO: 1 (Figure 14 and Example 11 page 60); and targeting of the heterologous mannan synthase encoded by SEQ ID NO: 2 to the Golgi of transgenic somatic soybean embryos and functional characterization of heterologously expressed guar mannan synthase by measurement of beta-1,4 mannan biosynthesis in transgenic soybean somatic embryos and transgenic soybean seeds (Examples 18 and 19 pages 73-76).

Applicants do not teach any other polynucleotides encoding a mannan synthase sequence other than SEQ ID NO: 1 encoding SEQ ID NO: 2.

The state-of-the-art is such that one of skill in the art cannot predict whether putative processive beta glycosyl-transferases encode an enzyme that catalyzes galactomannan or some other hemicellulose product because the genes encoding this superfamily of enzymes may represent up to 1% of the total number of genes active in the genome of a plant (Saxena I. *et al.*, Cell Biology; 2000, Vol. 3; pp. 523-531; see page 523 column 1) and although various approaches have been pursued, there are only a few examples of successful isolation and characterization of polynucleotides encoding polypeptides that synthesize noncellulosic polysaccharides of the plant cell wall (Liepman A. *et al.* PNAS; February 8, 2005; Vol. 102, No. 6 pp. 2221-2226; see page 2221 columns 1 and 2); and that the state of the art for drawing distinctions between family members of processive beta glycosyl-transferases sufficient to identify specific activity is not well resolved (Dhugga K. *et al.* Science; 16 January 2004; Vol. 303, pp. 363-366; see page 365 column 3).

Given the lack of guidance in the instant specification, the limited number of working examples and the unpredictability in the art, undue trial and error experimentation would be required for one of ordinary skill in the art to isolate sequences similar to a multitude of

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processive beta glycosyltransferases and test for mannan synthase activity by transforming a myriad of plants and analyzing for increases in expression patterns and product formation across any number of plant species to determine the identity of a putative beta-glycosyltransferase encoding polynucleotide.

Therefore, given the breadth of the claims; the lack of guidance and working examples; the unpredictability in the art; and the state-of-the-art as discussed above, undue experimentation would be required to practice the claimed invention, and therefore the invention is not enabled throughout the broad scope of the claims.

All claims are rejected.

The claims are deemed free of the prior art given the failure of the prior art to teach or reasonably suggest a polynucleotide of SEQ ID NO: 1 encoding a mannan synthase of SEQ ID NO: 2

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Kallis whose telephone number is (571) 272-0798. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Russell Kallis Ph.d
October 27, 2006

RUSSELL P. KALLIS, PH.D.
PRIMARY EXAMINER

Russell Kallis